IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PharmacyChecker.com LLC,	)	
	)	
Plaintiffs	)	
v.	)	
	)	**Case No. 7:19-cv-7577-KMK**
National Association of Boards of Pharmacy, *et. al*,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' JOINT MOTION TO DISMISS SHERMAN ACT § 1 CLAIM
AND THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY'S
MOTION TO DISMISS LANHAM ACT CLAIM

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Defendants National Association of Boards of Pharmacy ("NABP"), Alliance for Safe Online Pharmacies ("ASOP"), Center for Safe Internet Pharmacies, Ltd. ("CSIP"), LegitScript LLC ("LegitScript"), and Partnership for Safe Medicines, Inc. ("PSM") (collectively "Defendants") respectfully submit this Memorandum of Law in support of their joint motion to dismiss the first cause of action asserted in Plaintiff PharmacyChecker.com LLC's ("Plaintiff" or "PharmacyChecker") Amended Complaint ("Complaint") alleging violation of the Sherman Act, 15 U.S.C. § 1. Defendant NABP submits this memorandum in support of its motion to dismiss Plaintiff's second cause of action alleging a Lanham Act claim. 15 U.S.C. § 1125(a).

PRELIMINARY STATEMENT

Plaintiff's Sherman Act conspiracy claim—alleging that Defendants "jointly agreed" with "gatekeepers," including Google, Microsoft/Bing, Facebook, Mastercard, PayPal, and UPS, to eliminate Plaintiff from the alleged markets—must be dismissed on multiple independent bases. *First*, Plaintiff has not and cannot plead facts establishing "antitrust injury"—that is, a "loss" to its business that "stems from a ***competition-reducing*** aspect or effect of the defendant's behavior." Congress, the courts, and FDA regulations all agree that importation of foreign pharmaceuticals, even for personal use, is illegal and may jeopardize patient health and safety. Plaintiff's business is built on facilitating the unlawful importation of foreign pharmaceuticals. Its Complaint establishes this fundamental fact and, when questioned by the Court, Plaintiff conceded that its "primary" purpose is to "facilitate" unlawful importation. As "allegedly anticompetitive behavior [that] discourage[s] only unlawful importation of drugs and not lawful activity the Sherman Act was designed to protect" is not "an injury of the type that the antitrust laws were designed to remedy," Plaintiff cannot establish antitrust injury as a matter of law. *In re Canadian Import Litig.*, 470 F.3d 785, 788, 791 (8th Cir. 2006).

Second, Plaintiff fails to plead facts plausibly showing an agreement between Defendants or between Defendants and the so-called internet "gatekeepers" to do anything illegal. Plaintiff's boilerplate recitation of antitrust "buzzwords" and conclusory assertions do not meet the standard for surviving a motion to dismiss. Plaintiff cites wholly unilateral conduct and two innocuous trade group meetings involving some, but not all Defendants, back in 2011 and 2012, after which certain Defendants issued statements about combatting "rogue internet pharmacies." Other allegations baldly conclude that advocacy organizations with similar public policy and safety goals must have "coordinated" a "misinformation" campaign when they published information critical of unlawful drug importation. Plaintiff's list of unilateral conduct and vague trade group allegations cannot give rise to an inference of conspiracy.

Indeed, Plaintiff's conspiracy claim is entirely implausible. Plaintiff alleges that Defendants entered into agreements with a host of disparate companies—including Google, Microsoft/Bing, Facebook, Mastercard, PayPal, and UPS—with the express purpose of excluding Plaintiff from the alleged markets. At the core of Plaintiff's conspiracy claim is its argument, citing no factual support, that Defendant CSIP, a non-profit organization devoted to safe internet pharmacy practices, somehow strong-armed these large, multi-national corporations to boycott Plaintiff via CSIP's Principles of Participation. Plaintiff's theory concerning CSIP's purported power over its members is neither conceivable nor plausible, and without the participation of this cast of large internet "gatekeeper" corporations, Plaintiff's claim falls apart.

Third, Plaintiff's relevant market allegations are utterly conclusory, containing none of the legally required *facts* relating to product interchangeability, demand cross-elasticity, barriers to entry, or other pleading requirements. In the absence of properly pled markets, the Court cannot determine whether the Defendants' conduct had anticompetitive effects, thus requiring dismissal.

Critically, there is no way Plaintiff could amend its Complaint (again) to avoid dismissal. Given "[t]he costs of modern federal antitrust litigation," this Court should not "send[] the parties into discovery when there is no reasonable likelihood that the plaintiff[] can construct a claim from the events related in the complaint." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

Plaintiff also fails to state a Lanham Act claim against NABP. Plaintiff claims that NABP deceives consumers and internet "gatekeepers" by: (i) stating or implying that personal importation is illegal and/or unsafe; and (ii) "conflating" Plaintiff's site, which does not directly sell foreign drugs, with NRL sites that directly import into the U.S. *See* Compl. ¶¶ 126, 128, 130–132. Plaintiff cannot establish, as it must, that these statements are false, that they are statements made in commercial advertising, or that the statements misrepresent the nature of Plaintiff's "products." As noted, Plaintiff concededly "facilitates" unlawful drug importation. It thus cannot be false for NABP to state that purchasing drugs from unlawful sources, including those Plaintiff links to via its website, may be risky, unsafe, or illegal. Nor, given Plaintiff's stark concessions, could such statements somehow misrepresent the nature of Plaintiff's products. And, given that NABP is a non-profit policy organization whose statements are designed to educate the public about the congressionally and FDA-recognized dangers of unapproved drug use, its speech is constitutionally protected and thus cannot qualify as commercial speech under the Lanham Act.

BACKGROUND

I. The U.S.'s "Closed System" Regulatory Regime for Prescription Drugs.

Congress "create[d] a 'closed system' . . . for consumers in the United States." *Canadian Import*, 470 F.3d at 790 (citing *Vermont v. Leavitt*, 405 F. Supp. 2d 466, 472 (D. Vt. 2005)). "This 'closed system' ensures that approved prescription drugs are 'subject to FDA oversight' and are 'continuously under the custody of a U.S. manufacturer or authorized distributor,'" to ensure the quality of drugs used by American consumers is consistent and predictable. *Id.* at 790 (quoting

United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238, 1241–42 (N.D. Okla. 2003)). The Food and Drug Administration ("FDA") also has "repeatedly [] expressed the view that virtually all importation of drugs into the United States by individual consumers violates the [Federal Food, Drug, and Cosmetics Act ("FFDCA")] because the drugs are not approved in accordance with 21 U.S.C. § 355, are not labelled as required by 21 U.S.C. § 352, or are dispensed without a valid prescription in contravention of 21 U.S.C. § 353(b)(1)." *Canadian Import*, 470 F.3d at 788–89. While the FDA "might" exercise discretion to permit limited personal importation exceptions, it has *not* exercised this authority, and Plaintiff does not allege that any exception applies here.[1]

The FDA cautions that, "[w]ithout regulation of repackaging, storage conditions, and many other factors, drugs delivered to the American public from foreign countries may be very different from FDA approved drugs with respect to formulation, potency, quality, and labelling." *Id.* at 789. This system of overlapping regulations ensures the safety of drug supply by ensuring that approved drugs are "subject to FDA oversight" from the point of manufacture to the point of sale. *Id.*

The FFDCA prohibits the "introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded," as well as any drug that is not sold pursuant to an approved FDA application. *See* 21 U.S.C. § 331(a), 331(d) (citing 21 U.S.C. § 355, which requires all drugs to be sold pursuant to an application). The Act expressly prohibits importation of drugs, except under limited circumstances defined below and not applicable here. *Id.* § 333(b)(1)(A). Persons who violate these provisions are subject to injunctions, fines, or

[1] The FDA "might" allow importation of drugs "for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means," where there is "no known commercialization or promotion of the product to persons residing in the U.S.," where the product "does not present an unreasonable risk," where the consumer imports less than a three month supply, and where the consumer provides certain representations in writing to the FDA. U.S. Food and Drug Admin., *Personal Importation* (Aug. 3, 2018), https://www.fda.gov/industry/import-basics/personal-importation#UScitizen. Representations include written affirmation that the product is for personal use and either the name and address of the U.S. doctor responsible for the patient's treatment or evidence that the product is "for the continuation of treatment begun in a foreign country." *Id.*

imprisonment. *Id.* § 333(b)(1) (punishment of imprisonment "for not more than 10 years" or a fine of "not more than $250,000" for a knowing importation violation); *id.* § 333(a) (punishment of up to one year imprisonment and fine of not more than $1,000 for first violation of 21 U.S.C. § 331). This is evidenced, for example, by a non-prosecution agreement ("NPA") issued by the Department of Justice that targeted advertising by foreign pharmacies in the United States. *See* Compl. ¶ 48.[2]

The Eighth Circuit has held that Canadian prescription drugs are "not labeled in conformity with federal law" and "importation. . . is therefore prohibited." *Canadian Import*, 470 F.3d at 789 ("More fundamentally, that the Canadian drugs are mislabeled under federal law illustrates why the Canadian drugs are 'unapproved' drugs within the meaning of 21 U.S.C. § 355, and thus prohibited from importation on that basis as well."). Labelling violations are not "merely a 'hyper-technical' violations of the FFDCA." *Id.* at 790. Instead, labelling requirements "work in conjunction with the other statutory standards and FDA regulations to create a system that excludes noncompliant and potentially unsafe pharmaceuticals." *Id.* The *Canadian Import* court articulated why U.S. consumers cannot import drugs from Canada, though the drugs may *appear* functionally identical to drugs for sale in the U.S.:

> Before a new drug may be introduced into interstate commerce, the FDA must approve the manufacturing process, labeling, and packaging. 21 U.S.C. § 355(b)(1). The approval process addresses the chemical composition of the drug, *id.* § 355(b)(1)(B), (C), the drug's safety and effectiveness, *id.* § 355(b)(1)(A), and elements of the drug's distribution, such as "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing" of the drug, *id.* § 355(b)(1)(D), and the "labeling proposed to be used" for the drug. *Id.* §

[2] The NPA, relied upon by Plaintiff in its Complaint, is attached as Exhibit C to the Declaration of Erik T. Koons (Mar. 13, 2020). *See* Compl. ¶ 48 (referencing the NPA). The NPA was made public by the Department of Justice. A court may consider on a motion to dismiss "documents incorporated in [the complaint] by reference," as well as "documents that the plaintiffs either possessed or knew about and upon which they relied in bringing the suit." *Rothman v. Gregor*, 220 F.3d 81, 88 (2d Cir. 2000). The Court may also consider "matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). A court "may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Civ. P. 201.

> 355(b)(1)(F). The approval process is specific to each manufacturer and each product. *See* 21 C.F.R. § 314.50.
>
> Drugs that are manufactured and distributed in Canada are not approved pursuant to this statutory framework. The approval process requires, among other things, that a manufacturer provide "the proposed text of the labeling for the drug." 21 C.F.R. § 314.50(c). Because foreign labeling differs from domestic labeling, approval granted to a particular manufacturer for a particular product to be distributed in the United States does not constitute approval of another drug — even one with the same chemical composition — to be distributed in Canada with different labeling, and then imported into the United States.

Id. at 789–90.

The authority to allow any importation of drugs from outside this "closed system" is vested in the Secretary of Health and Human Services ("Secretary"). Instances in which the Secretary can allow for importation are limited and strictly controlled pursuant to federal law—they do not make legal the importation of drugs from foreign countries for personal use. For example, U.S. law prohibits "reimportation" of drugs manufactured by U.S. companies and then exported, except by the manufacturer or with the approval of the Secretary. 21 U.S.C. § 381(d)(1)(A), (d)(2). Drugs manufactured outside the U.S. cannot be "imported into the United States for commercial use. . . unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States," or with the authorization of the Secretary for drugs on the drug shortage list. *Id.* § 381(d)(1)(B). The Secretary also has the authority to permit the importation of drugs in cases of emergencies. *Id.* § 381(d)(2).

Under a 2003 federal law, the Secretary is permitted to allow broader importation from Canada, but not any other country, and only after "certif[ying] to the Congress that the implementation of" that law will "(A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in cost of covered products to the American consumer." 21 U.S.C. § 384(b) (allowing for importation under this Section only from Canada); *id.* § 384(l) (requiring the Secretary to make certifications before implementing this section). The Secretary

declined to implement this section until December 2019, when HHS issued a Notice of Proposed Rulemaking for controlled importation by states or other governmental entities. *See* Dep't of Health and Human Svcs., Food and Drug Admin., Importation of Prescription Drugs, Proposed Rule ["HHS Proposed Drug Importation Rule"], 84 Fed. Reg. 70796 (Dec. 23, 2019) (attached as Exhibit D). This proposed rule has yet to become final.[3] Drugs imported pursuant to this rule would be imported by FDA-overseen state or local governmental entities, *not* individuals, subject to strict testing requirements, and bear labelling for legal sale in the U.S. or Canada. *See id.* at 70797.

The Secretary explained that the HHS Drug Importation Rule "*is not proposing to implement the personal importation* provisions in section 804(j) through [the] rulemaking," warning that "[m]edications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges for FDA *and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers*." *Id.* at 70800 (emphasis added). The Secretary went on to warn against "pharmacies that sell medication at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by pharmacies licensed by a State in the United States," and noted that while many pharmacies purport to be from Canada or sell drugs approved in Canada, those "drugs. . . in many instances

[3] The statute places strict limitations on the imports that the Secretary may permit. The statute permits the Secretary, in consultation with other federal officials, to promulgate regulations "permitting pharmacists and wholesalers. . . to import prescription drugs from Canada." 21 U.S.C. § 384(b). Any regulation is subject to congressionally-mandated requirements, including that importers submit detailed information to HHS about the name, ingredients, quantity, dosage, origin, destination, price, control numbers, information enabling the tracing of each prescription drug to the manufacturer, and information about batch testing and degradation for each prescription drug. *See id.* § 384(d)(1). Imported drugs must undergo "testing. . . at a qualified laboratory" to authenticate the drug and to "confirm that the labeling. . . complies with the labeling requirements" of the FFDCA and that the labels are "supplied by the manufacturer. . . to the pharmacist or wholesaler." *Id.* §384(e)(2). Under Section 384, the Secretary could permit importation from Canada by individuals, but only "from a seller registered with the Secretary," only approved drugs, *and* only drugs from registered manufacturing sites. *Id.* § 384(j)(3). The Secretary can only implement these provisions by making additional certifications to Congress about health, safety, and cost. *See id.* § 384(l). The Secretary has not implemented or proposed to implement the personal importation provisions.

are not actually from Canada and not approved by [the Canadian FDA analogue]. . . . A 2005 FDA analysis of drugs imported through International Mail Facilities revealed that while nearly half of the imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of those drugs originated elsewhere and were fraudulently represented as Canadian." *Id.*

II. Sherman Act Section 1 and Lanham Act Allegations.

A. Plaintiff's Verification and Price Comparison Services Provide a Mechanism for U.S. Consumers to Access Foreign Pharmaceuticals Outside the "Closed System" of the U.S. Pharmaceutical Regulatory Regime.

Plaintiff alleges that it provides "accreditation to safe online pharmacies worldwide," and connects "consumers who are contemplating purchasing their prescription medications from an online pharmacy website" to those pharmacies "regardless of the pharmacy's or the consumer's location." Compl. ¶¶ 60, 33. Plaintiff accredits "both foreign and domestic" pharmacies that are "licensed and regulated in their jurisdiction, sell lawfully manufactured products, follow good pharmacy practices, require prescriptions, and do not sell controlled substances[4] internationally." *Id.* ¶ 40. Once it has accredited a pharmacy, Plaintiff's website "allows consumers worldwide to find the lowest prices for their prescription medications [from Plaintiff's accredited pharmacies], whether dispensed in the United States or abroad." *Id.* ¶ 5. Plaintiff touts that "international online pharmacies" make "lower-price" drugs "accessible to patients world-wide [] and particularly to U.S. patients. . . ." *Id.* ¶ 21. Plaintiff contrasts its accreditation services with those offered by companies like NABP, which it alleges are "of little utility for many consumers—those seeking to find the lowest possible drug prices—because NABP [does] not accredit Canadian or other non-U.S. pharmacies that sell medicine into the United States." *Id.* ¶ 39.

Plaintiff also alleges that it participates in the "market for comparative prescription drug

[4] Controlled substances are substances scheduled by the DEA. Some prescription drugs contain controlled substances, but most do not.

pricing information." *Id.* ¶ 30. Plaintiff's price comparison services "include the prices of medications of PharmacyChecker.com-accredited pharmacies, which are located in the United States *and abroad*. . . ." *Id.* ¶ 43 (emphasis added). Plaintiff does not allege that any Defendant provides a similar service. *Id.* ¶ 34 (alleging one ASOP *member* as competitor). Instead, Plaintiff's competitors here are non-parties including GoodRx, Drugs.Com, WellRx, and eDrugsearch. *Id.*

Plaintiff concedes that prescription drug importation is "restricted under some circumstances," but offers the red-herring that "the law is generally applied only to bulk commercial importations, not personal importations by consumers." Compl. at 2; *see also id.* ¶ 24 (describing clear guidance from the FDA barring almost all personal importation as a "legal gray area"). Plaintiff admits that drugs "manufactured identically to the specifications of an FDA-approved drug" but not appropriately labelled are "misbranded," and that foreign drugs can include formulations not approved for sale in the U.S. *Id.* ¶¶ 55–56. Yet Plaintiff claims that "drug importation is not, by itself, illegal" because "FDA-approved drugs can be and are imported." As explained, this is not an accurate description of the legality of personal importation. There are *some* possible exceptions to the general rule blocking foreign drug importation, *see id.* ¶ 57, *see also supra* note 1, but Plaintiff does not assert that all or even some of the sales by its accredited foreign pharmacies they connect with U.S. consumers fall into those exceptions.

Plaintiff makes the conclusory statement that it does not "import[] []or facilitate[] the import of any products." Compl. ¶ 52. Yet, Plaintiff's Complaint's *factual* allegations and admissions at the PI hearing clearly establish it connects U.S. consumers seeking to purchase pharmaceuticals from foreign pharmacies with foreign pharmacies that sell to U.S. consumers.[5]

[5] A court may "take judicial notice [when considering a 12(b)(6) motion] of admissions and concessions already made in [the current] action; no rule of procedure requires a court to pretend these do not exist." *Realnetworks, Inc. v. DVD Copy Control Ass'n, Inc.*, No. C 08-4548 MHP, 2010 WL 145098, at *4 (N.D. Cal. Jan. 8, 2010); *see also Ventre v.*

See, e.g., id. ¶ 27 ("PharmacyChecker.com … provides patients with (1) a way to reliably identify online pharmacies that operate safely *worldwide,* and (2) direct access to comparative drug price information *not limited to U.S. pharmacies* . . . .) (emphasis added); *id.* at ¶ 108 ("PharmacyChecker.com's exclusion from the market means reduced consumer choice . . . and fewer and more restricted options for alternative sources of lower-priced prescription drugs both U.S.-based and *abroad*.") (emphasis added). That Plaintiff's business model is based on facilitating illegal personal importation was amplified by Plaintiff at the preliminary injunction hearing, when the Court asked: "I don't understand what the reason is to provide information, including the link, except to facilitate that purchase. [A:] That is likely ***the primary reason***, your Honor." PI Tr. at 65:24–66:3 (emphasis added); *id.* at 65:21-23 ("some international pharmacies selling into the United States, that may be illegal, but providing information is not. It may be bad policy."); *id.* at 86:15–18 (Court: "And indeed, when I asked counsel…what would be the purpose of providing the information other than to allow people to do something that's illegal, the answer is, there isn't.").

B. The Alleged Conspiracy and NABP's "False Advertising."

Plaintiff alleges that NABP and LegitScript provide verification to licensed pharmacies that wish to operate online, among other things. *See* Compl. ¶ 6 (discussing NABP); *id.* ¶ 9 (discussing LegitScript). CSIP offers "data-sharing tools about 'suspected illegitimate online pharmacy websites,'" coordinates "communications campaigns," and has a membership that includes major companies like "Google, Facebook, Microsoft, Facebook, Mastercard, and UPS." *Id.* ¶¶ 8, 75. ASOP brings together "key stakeholders to compile data" and "address the problem

Datronic Rental Corp., No. 92–3289, 1995 U.S. Dist. LEXIS 20323, at *18–19 (N.D. Ill. Dec. 5, 1995) (Defendant relies on "admissions by plaintiffs' counsel contained within the record of this case.... Since this court may properly consider ... items appearing in the record of the case ... it declines to convert the motion to dismiss into a motion for summary judgment.").

of online drug sellers/counterfeits." *Id.* ¶ 7. PSM is an issue-advocacy "nonprofit organization that has orchestrated a wide-reaching campaign against foreign drug imports." *Id.* ¶ 10. Defendants NABP, ASOP, CSIP, and PSM are all nonprofits. *Id.* ¶ 12.

Plaintiff alleges a scheme by Defendants to exclude PharmacyChecker by "using shadow regulation—private agreements with key internet gatekeepers—to manipulate and suppress the information available to consumers seeking information about lower-cost, safe prescription medicine." *Id.* 1–2. Plaintiff alleges that Defendants' "primary purpose is to restrain competition by ... persuading or coercing others not to do business with their targets [allegedly, Plaintiff] or to cut them off from essential resources necessary to compete." *Id.* ¶ 29. Yet Plaintiff itself has worked with these "gatekeepers" to exclude bad actors, providing verification services to Google, Bing, and Yahoo beginning in 2006, to help prevent rogue pharmacy advertising.[6] *Id* ¶ 48.

Throughout the alleged decade-plus-long scheme, Plaintiff alleges no meetings between all of the Defendants.[7] Instead, Plaintiff alleges just two instances in which one Defendant met with another. The first was a 2011 meeting between NABP, CSIP, and some CSIP members. *Id.* ¶ 71. The second was a "2012 meeting, [where] NABP and ASOP [allegedly] affirmed their agreement to continue to work together to restrain competition by online pharmacies." *Id.* ¶ 73. There, NABP and ASOP allegedly "discussed numerous plans for actions that they intended to

[6] In 2011 Google entered into a non-prosecution agreement for allowing foreign pharmacy advertisers to run online ads in the United States, including those "that [] did not qualify for certification by PharmacyChecker.com." Compl. ¶ 48; *see also* note 2, *supra* and accompanying text. Plaintiff's characterization of the NPA is deficient. As explained in *supra* note 2, the Court may take judicial notice of the NPA. The NPA states that "[w]hile PharmacyChecker did not certify online pharmacies that shipped controlled prescription drugs, Canadian or otherwise, PharmacyChecker did certify advertisers of non-controlled prescription drugs, including distributors of non-controlled prescription drugs located in Canada. As a result, [Google] knowingly permitted Canadian online pharmacies, certified by PharmacyChecker, to advertise the sale of non-controlled prescription drugs through AdWords to U.S. consumers." NPA ¶ 2(l). The NPA also stated that "except under very limited circumstances . . . it is unlawful for pharmacies outside the United States to ship prescription drugs to customers in the United States." NPA ¶ 2. It was credited for adopting VIPPS in 2010 "to exclude pharmacy advertisers that import or dispense prescription drugs in violation of United States law. NPA ¶ 8.

[7] PSM is not alleged to have been part of any meetings, but it did issue press releases that include information from other alleged co-conspirators' public press releases. Compl. ¶¶ 71–73, 77.

undertake in conjunction with their co-conspirators to further limit competition from online pharmacies." *Id.* ¶ 72. There are no allegations of even bilateral meetings of Defendants after 2012. *See generally*, Compl. It apparently took NABP six years to implement this scheme from 2011 or 2012 and "[b]lacklist[] PharmacyChecker," something it had also done for a period of months in 2010. *See id.* ¶¶ 79, 87.

Plaintiff points to discrete e-mails and press releases from the 2000s and early 2010s where Defendants express similar goals of limiting illegal prescription drug sales, characterizing them as "[a]greements . . . of Defendants and Co-Conspirators" and "[a]ctions in [f]urtherance of [a] [c]onspiracy." *Id.* at 26, 32. Between 2013 and 2014, NABP, ASOP, CSIP, LegitScript, as well as Pfizer, Eli Lilly, Gilead Sciences, Janssen, Merck, the International Pharmacy Federation and "other unnamed 'stakeholders'" allegedly sought to create a ".pharmacy" domain through ICANN that advertisers and merchants could use to identify legitimate online pharmacies. *Id.* ¶ 80. In 2015, NABP unilaterally sent a letter asking ICANN to "take down" other pharmacy domains that lacked NABP or LegitScript approval. *Id.* ¶ 81; *see also id.* ¶¶ 96–99 (discussing .pharmacy domain extension). ICANN declined. *Id.* ¶ 81. The .pharmacy extension is not available to foreign pharmacies that ship prescription drugs to US patients. *Id.* ¶ 97. CSIP member companies MasterCard, Google, and UPS "have jointly agreed to only allow online pharmacies with a '.pharmacy' address to advertise, take payments, and ship products."[8] *Id.*

In 2015, several Defendants put out press releases over a period of several months linking Plaintiff to "an indictment related to illegal wholesale drug importation." Compl. ¶ 85. ASOP and LegitScript jointly issued a release on August 18, NABP published a "blog post" the next day, and

[8] These CSIP member companies, unlike CSIP itself, are also not alleged to be part of the purported "conspiracy." Plaintiff does not allege any facts to support its conclusory allegation that any of CSIP's members ever agreed to *only* use .pharmacy for any purpose or that CSIP worked on the creation of ".pharmacy." *See* Compl. ¶ 97.

CSIP published a blog post in September and another in October. *Id.* Plaintiff alleges these sequential actions were "coordinated." *Id.* Plaintiff does not allege any meetings, communications, "actions in furtherance of the conspiracy," or any conduct in 2016. Two years later, in 2017, one pharmacy allegedly told Plaintiff that NABP would not certify that pharmacy under NABP's proprietary VIPPs program if it also advertised affiliation with Plaintiff. *Id.* ¶¶ 82–83. Plaintiff posits that "NABP or LegitScript" reported Plaintiff to a "security vendor" to have Plaintiff's website characterized as "not safe" for firewalls and network filters, though Plaintiff admits the vendor "would not name" the company that made the report. *Id.* ¶ 84.

In December 2018, NABP added PharmacyChecker.com and an affiliated blog to its "not recommended sites list" ("NRL"). *Id.* ¶ 87. The NRL states, with respect to Plaintiff's site and at least 11,000 other webpages, *inter alia*: "Avoid these websites" because they "appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards," *id*. ¶ 119, 131, and that NRL websites "may: Dispense prescription medicine without a prescription; Dispense foreign or unapproved medicine[; or] Refer/link patients to sites that facilitate the dispensing of prescription medication in violation of state or federal law or NABP standards," *id*. ¶ 119. A September 2019 version of the NRL states that "[t]he following sites are all known to be unsafe," *id.* ¶ 121, and that "[u]sing websites on the NRL to purchase drugs may put you or your loved ones at risk," *id.* ¶ 123. Plaintiff alleges that NABP's website encourages consumers to "[p]urchase medication from legitimate websites online," and provides a link to a list of pharmacy websites allegedly approved by NABP's VIPPS program. *Id.* ¶ 134; *see also infra* Table I (listing all alleged NABP statements); Exhibits E–H (screenshots from videos provided by Plaintiff in Compl. ¶ 123 n.10 and ¶ 95 n.6).

Plaintiff does not allege that NABP coordinated with any other Defendant when it added

Plaintiff to the NRL. Plaintiff *does* allege that some CSIP *members*—not named as defendants in the Complaint and not alleged to be a part of any conspiracy—subsequently limited Plaintiff's visibility or provided warnings in searches that included Plaintiff. *Id.* ¶ 92.[9]

CSIP maintains a not recommended site, and allegedly ran advertisements targeting Plaintiff in June and July of 2019, asking consumers to "Choose a Safe Pharmacy" and stating "It's Not Worth the Risk." *Id.* ¶¶ 93–94. Those ads were funded by a grant from Google, a CSIP member; Plaintiff does not allege these ads were coordinated with any other Defendant. *Id.* ¶ 93.

LEGAL STANDARD ON MOTION TO DISMISS

To survive a motion to dismiss, a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. This "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 557). "'[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct,'…dismissal is appropriate." *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010) (quoting *Iqbal*, 556 U.S. at 679). "'Determining whether a complaint states a plausible claim for relief [is]…a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Pen. Ben. Guar. Corp. v. Morgan Stanley Inv. Mgmt. Inc.*, 712 F.3d 705, 718 (2d Cir. 2013) (quoting *Iqbal*, 556 U.S. at 679).

Courts begins by "identifying the allegations in the complaint that are not entitled to the presumption of truth," *Iqbal*, 556 U.S. at 680, which include formulaic recitations of the elements of the claim, "the legal conclusions drawn from the facts," "unwarranted inferences," as well as

[9] Plaintiff also claims that additional non-parties, including Bing, "incorporated" the NRL into their search results and displayed warning boxes stating that NABP includes Plaintiff's website on the NRL. Compl. ¶ 134.

"unreasonable conclusions [] or arguments." *Glassman v. Arlington County*, 628 F.3d 140, 146 (4th Cir. 2010). Where an allegation constitutes "wild speculation," it should be considered "wholly inadequate to support any sort of claim." *See Charles v. Levitt*, No. 15-cv-9334, 2016 WL 3982514, at *7 (S.D.N.Y. July 21, 2016). A court need not consider allegations that conflict with documents properly considered on a motion to dismiss. *Twombly*, 550 U.S. at 568 n.13.

ARGUMENT

I. Plaintiff Did Not and Cannot Adequately Plead "Antitrust Injury."

Plaintiff must plead sufficient facts to establish "*antitrust* injury," that is, "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990) ("ARCO") (emphasis in original); *Daniel v. American Bd. of Emergency Medicine*, 428 F.3d 408, 438 (2d Cir. 2005) (same). A plaintiff must adequately allege antitrust injury in *all* antitrust actions, regardless of whether a court evaluates the claim under a *per se*, inherently suspect, quick look, or rule of reason standard. *See World Wrestling Ent., Inc. v. Jakks Pacific, Inc.*, 425 F. Supp. 2d 484, 519–520 (S.D.N.Y. 2006) (KMK) ("The *per se* rule is a method of determining whether § 1 of the Sherman Act has been violated, but it does not indicate whether a private plaintiff has suffered antitrust injury ....") (quoting *ARCO*, 495 U.S. at 341–42).

The Complaint demonstrates that Plaintiff's business is modeled on facilitating unlawful conduct. As a matter of law, Plaintiff therefore can plead no facts establishing that any of Defendant's alleged conduct caused harm of the kind the antitrust laws were intended to prevent—either to Plaintiff's own business *or* to consumers. Rather, it is the "reality of the regulated environment," *i.e.*, the illegality of foreign drug importation under federal and state law, which caused any alleged "injury" to Plaintiff or to the market. As Plaintiff cannot rectify this pleading deficiency through further amendment, the Court should dismiss its claim with prejudice.

A. Plaintiff Did Not and Cannot Sufficiently Allege Injury to Its Business When the Alleged Conduct Merely Prevents It from Facilitating Unlawful Conduct.

Plaintiff did not and cannot sufficiently allege antitrust injury where its asserted harm arises out of Defendants' alleged acts suppressing unlawful drug importation. The facts and law are clear: Plaintiff concedes that its "primary" reason for providing price verification and accreditation information is to "facilitate" unlawful foreign pharmaceutical purchases by U.S. consumers. PI Tr. at 65:24–66:3. "Allegedly anticompetitive behavior [that] discourage[s] only unlawful importation of drugs and not lawful activity the Sherman Act was designed to protect" is not "an injury of the type that the antitrust laws were designed to remedy." *Canadian Import*, 470 F.3d at 788, 791.

Personal importation of foreign pharmaceuticals into the U.S. is unambiguously illegal. *See supra* Background § I. Plaintiff admits that its business model is built on "accrediting" and providing price comparisons that include foreign pharmacies not bound by FDA regulations that cannot legally sell into the U.S. *See* Compl. ¶¶ 40–41 (conceding that Plaintiff accredits "foreign" pharmacies and that it is "a recognized authority . . . about online pharmacies, particularly those that sell medicine internationally. . ."); *see also supra* note 5 and accompanying text. Plaintiff describes its business model as "unique"—allegedly that of a "maverick"—precisely because unlike NABP and LegitScript, it recommends more than just "U.S.-based online pharmacy websites" to consumers, with the effect of facilitating importation. *See* Compl. ¶ 33; *see also infra* note 13 (discussing the inapplicability of U.S. antitrust laws to wholly foreign commerce).

The Eighth Circuit has squarely held that alleged harm resulting from U.S. law prohibiting pharmaceutical importation is not the type of injury that the antitrust laws are designed to remedy. *See Canadian Import*, 470 F.3d at 791. The *Canadian Import* case involved a claim by a putative class of plaintiffs alleging that drug manufacturers conspired in violation of the Sherman Act to

"suppress the importation of Canadian prescription drugs for personal use." *Id.* at 787. Like Plaintiff here, the class in *Canadian Import* alleged, *inter alia*, that defendants created "blacklists" of pharmacies suspected of selling to U.S. consumers. *See id* at 788. The district court dismissed the conspiracy claim under Rule 12(b)(6) for lack of antitrust injury and standing, holding that, because the "FDA repeatedly has expressed the view that virtually all importation of drugs into the United States by individual customers violates the FFDCA," the plaintiffs' alleged injury was "caused by the federal statutory and regulatory scheme adopted by the United States government, *not by the conduct of the defendants*." *Id*. at 788–89, 791 (emphasis added). As in *Canadian Import*, Plaintiff's claimed injury here is predicated on illegal conduct—facilitating importation from foreign countries in clear violation of U.S. law. *Canadian Import* thus instructs that Defendants' alleged "suppression" of Plaintiff's facilitation of foreign drug importation is not the type of injury the antitrust laws are intended to protect.[10]

Other courts have dismissed antitrust complaints for lack of antitrust injury where the plaintiff's business model was built around the facilitation of unlawful conduct. In *Maltz v. Sax*, the Seventh Circuit had before it defendants' motion to dismiss plaintiff's claim alleging that defendants conspired to injure its business of manufacturing gambling "punch boards" at a time when gambling was illegal under federal law. 134 F.2d 2, 5 (7th Cir. 1943). The defendants argued plaintiff could not maintain his claim because "the use and sale of" gambling devices was "against public policy and unlawful." *Id*. at 3. Like Plaintiff here, the plaintiff in *Maltz* argued that, while gambling itself may have been unlawful, manufacturing the punch boards was not, and

[10] Similarly, where a plaintiff suffers an injury from "the realities of the regulated environment"—rather than a defendant's actions —there can be no antitrust injury. *See Pittsburgh v. W. Penn Power Co*., 147 F.3d 256, 265 (3d. Cir. 1998) (affirming Rule 12 dismissal); *see also Biocad JSC v. F. Hoffman-La Roche*, 942 F.3d 88, 104 (2d Cir. 2019) (Katzman, C.J., concurring) (affirming Rule 12 dismissal, holding "[c]ourts often find a lack of antitrust injury when it views a regulatory barrier, rather than the defendant's alleged anticompetitive activities, as the cause of the plaintiff's [harm]").

thus, he could prove injury to his business. *See id.* at 4, 5; PI Tr. at 65:20–23 (Plaintiff: while importation "may be illegal, … providing information is not."). The *Maltz* court refused to play such semantic games, holding that, "[w]hile the business of making and selling gambling machines is not in itself gambling, "[p]laintiff's business was the making and selling of goods which could only be used by purchasers in furtherance of the business of gambling…. Plaintiff has no legal rights in [the] business…. Therefore defendants could not invade them." 134 F.2d at 5.

Similarly, courts have dismissed complaints where plaintiffs alleged that defendants' conduct prevented them from marketing technology that facilitated the illegal piracy of music and movies. In *Realnetworks, Inc. v. DVD Copy Control Ass'n, Inc.*, the plaintiff developed a product that allowed consumers to copy DVDs and store them on their computers. No. C 08-4548 MHP, 2010 WL 145098, at *1 (N.D. Cal. Jan. 8, 2010). When studios that produced DVD movies refused Realnetworks' request for licenses that would permit consumers to use the device, the plaintiff sued the studios alleging an unlawful group boycott under the Sherman Act. *Id.* at *2. The court held that the plaintiff's "purported injury" flowed not from the defendants' conduct, but "from its own decision to manufacture and traffic in a device that is almost certainly illegal…." *Id.* at *6. The court dismissed Realnetworks' conspiracy claim pursuant to Rule 12 and denied leave to amend, holding that, as a result of regulatory barriers, "there [was] no allegation Real could make that would give it antitrust standing even if it could otherwise plead a plausible claim under Rule 8." *Id.* at *8; *see also Pearl Music Co., Inc. v. Recording Industry Ass'n of America, Inc.*, 460 F. Supp. 1060, 1068 (C.D. Cal. 1978) (no "standing or capacity" to bring a suit against the Recording Industry Association of America ("RIAA") when the RIAA refused to grant it a license to continue business practices that were "totally illegal" in 49 states; even when plaintiff alleged that some of its business was lawful, "[t]he almost total magnitude of this illegal conduct by plaintiffs ma[de]

their miniscule conduct that may be legal, insignificant. . . ."); *Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1111 (6th Cir. 1989) (affirming Rule 12 dismissal where patent laws, not alleged conduct, caused plaintiff's exclusion from U.S. market).

Plaintiff's alleged harm flows from "its own decision" to facilitate conduct "that is almost certainly illegal." *See Realnetworks*, 2010 WL 145098, at *1. As a result, Plaintiff's business has been "suppressed," if at all, by the realities of the regulated environment, not Defendants' alleged conduct. Plaintiff thus cannot establish harm that the antitrust laws were intended to address.

B. Plaintiff Did Not and Cannot Adequately Allege Harm to Competition.

In addition to injury to itself, "a plaintiff can recover only if the loss stems from a *competition-reducing* aspect or effect of the defendant's behavior." *ARCO*, 495 U.S. at 344 (emphasis added); *Mahmud v. Kaufmann*, 607 F. Supp. 2d 541, 554 (S.D.N.Y. 2006) (a plaintiff must show "injury to competition; demonstrating injury only to individual competitors is insufficient."). Courts have uniformly held that "an individual plaintiff personally aggrieved by an alleged anti-competitive agreement has not suffered an antitrust injury unless the activity has a wider impact on the competitive market." *Eichorn v. AT&T Corp.*, 248 F.3d 131, 140 (3d Cir. 2001). The antitrust laws "were enacted for the protection of competition, not competitors." *Brunswick Corp. v. Pueblo Bowl-o-Mat, Inc.*, 429 U.S. 477, 488 (1977). Courts "insist[] on proof of *harm to the whole market*" to "fulfill[] the broad purpose of the antitrust law" to protect "competition in general," not merely "individual competitors." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis added).

Plaintiff claims that Defendants' alleged "restraints" on Plaintiff cause the suppression of "balanced information about online international pharmacy websites," which consumers would use, absent the restraints, to buy lower priced prescription drugs from online pharmacies in Canada and elsewhere. Compl. ¶ 107(b); *see also id.* ¶ 107(d) ("[c]onsumers pay far higher prescription

drug prices…."); *see generally* ¶¶ 107(a) – (h) (restating foregoing alleged harms); ¶ 108. Even if Plaintiff could show that U.S. consumers were forced to pay higher prescription prices as a result of Defendants' alleged conduct, such an injury is not harm in either of Plaintiff's alleged relevant product markets,[11] and consumers' purported inability to purchase foreign drugs (or use Plaintiff's information to facilitate those purchases) does not constitute antitrust injury as a matter of law. The *Canadian Import* case rejected an identical theory of market-wide injury:

> [P]laintiffs have not established antitrust standing to pursue their federal antitrust claims. Plaintiffs allege that they are injured by increased prices for prescription drugs in the United States, which they say result from their inability to import less expensive drugs distributed by Canadian pharmacies. As we have explained, however, the importation of drugs from Canada is prohibited by federal law. The absence of competition from Canadian sources in the domestic prescription drug market, therefore, is caused by the federal statutory and regulatory scheme adopted by the United States government, not by the conduct of the defendants. Consequently, the alleged conduct of the defendants did not cause an injury of the type that the antitrust laws were designed to remedy.

470 F.3d at 791.[12]

Plaintiff has not alleged any credible price, quality, or output effects in the market for either pharmacy verification services or price comparison information. *See generally* Compl. There are no allegations that pharmacies were forced to pay higher fees for "verification services," nor are there any factual allegations establishing that (i) consumers were actually forced to pay more for price comparison information; or (ii) drug purchasers could not have turned to a host of alternatives to the Plaintiff to find these ubiquitous lower-cost foreign internet pharmacies. *Id.* No Defendant even participates in the price comparison market. *Id.* ¶ 35. There are conclusory

[11] Plaintiff's market definitions are themselves deficient. *See infra* § III.

[12] Plaintiff makes the conclusory assertion that "consumers pay far higher prices for drugs in the related market for prescription drugs – even if they are shopping only for U.S. based pharmacies" because Defendants' conduct had the effect of "suppress[ing] price competition from international pharmacies." Compl. ¶ 107(d). The Court should reject these allegations. Plaintiff's allegations here are conclusory and devoid of any factual support. And this claim asserts a third relevant product market, the market for prescription drugs, which Plaintiff has not alleged. Further, foreign pharmacies cannot lawfully compete with U.S. pharmacies for U.S. consumers, on price or otherwise.

allegations that Defendants' conduct makes "information enabling consumer comparisons of pharmacies more difficult and . . . more costly to obtain," but those allegations are devoid of facts, and presuppose the utility and indispensability of Plaintiff's product. *See id.* ¶ 107a. And it would not be helpful for consumers to be able to access "the lowest prices available online via PharmacyChecker," *see id.*, when those low prices come from pharmacies from which consumers cannot lawfully purchase.[13]

II. Plaintiff Fails to Plead Facts Plausibly Showing Unlawful Concerted Action—Fatal to Its Conspiracy Claim.

It is black letter law that the antitrust laws contain "a basic distinction between concerted and independent action." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984). For its Section 1 claim, Plaintiff must allege sufficient facts that Defendants had a "conscious commitment to a common scheme designed to achieve an unlawful objective." *Anderson News, LLC v. American Media, Inc.*, 680 F.3d 162, 184 (2d Cir. 2012) (internal quotation omitted). As the Supreme Court explains, this "requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made.... [It requires] enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement." *Twombly*, 550 U.S. at 545. Plaintiff presents an implausible conspiracy theory that requires unwarranted inferences from facts demonstrating only unilateral conduct, lawful coordination, and parallel action in line with Defendants' independent interests.

[13] Plaintiff also seeks to apply U.S. antitrust laws to Defendants' alleged conduct for harm consumers allegedly suffered outside the U.S. *See* Compl. ¶ 61. But the U.S. antitrust laws do not reach outside the U.S. and Plaintiff's claims to this effect are substantively deficient. *See Biocad*, 942 F.3d at 94–95 (dismissing plaintiff's Sherman Act claim based on foreign conduct under the FTAIA, explaining that "if a plaintiff's claims are barred by the FTAIA, the plaintiff has failed to state a claim for relief as a matter of law"); *de Atucha v. Commodity Exch., Inc.*, 608 F. Supp. 510, 518 (S.D.N.Y. 1985) ("Congress did not contemplate recovery under the antitrust laws by an individual who traded, and was injured entirely outside of [U.S.] commerce."). Simply, the FTAIA "excludes from the Sherman Act's reach much anticompetitive conduct that causes only foreign injury." *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 158 (2004). It does so by "lay[ing] down a general rule placing *all* (nonimport) activity involving foreign commerce outside the Sherman Act's reach." *Id.* at 162 (emphasis in original).

Plaintiff implausibly alleges that, over the course of more than a decade, Defendants "coerced" a host of differently situated "gatekeeper" companies—including Google, Facebook, Microsoft/Bing, Mastercard, PayPal, *and* UPS—to enter into "agreements" for the express purpose of excluding Plaintiff from the alleged relevant markets. Compl. at 1–2 (alleging "defendants… [reached] private agreements with key internet gatekeepers—to manipulate and suppress the information available to consumers seeking information about lower-cost, safe prescription medicine"); *id.* ¶ 8 (defining "gatekeepers" as "Google, Microsoft, Facebook, Mastercard, and UPS."); ¶¶ 26 and 73(a) ("coerced" and "persuaded"). While these "gatekeepers" are purportedly essential to the successful operation of the alleged conspiracy, Plaintiff names none of them as Defendants. *Id.* ¶¶ 8, 26, 67, 73, 97, 101–114.

Plaintiff alleges that, through CSIP's voluntary[14] "Principles of Participation," CSIP was able to exert enough control over Microsoft/Bing, Google, and the other "gatekeepers" to "coerce" each to boycott Plaintiff.[15] Compl. ¶¶ 75, 93; *see also* PI Tr. at 21:3–25 (Regarding Bing, "we would argue it's been compelled, your Honor."); ([Court:] "CSIP has the leverage to control Bing and Google?...[A:] Yes, your Honor."); (CSIP is "not a voluntary organization necessarily, but …entities like Bing, *and these other Internet gatekeepers*, to be a member of CSIP, they need to

[14] The Principles themselves (as they were in effect at the time the Amended Complaint was filed) emphasize repeatedly that they are entirely voluntary, not binding on CSIP's members, subject to the members' respective policies and relevant law, and "describe some model practices that companies *may adopt* to help CSIP achieve its goals." *See* Declaration of Marjorie Clifton, dated March 13, 2020, at ¶ 3 (emphasis added).

[15] Plaintiff made additional concessions regarding the contours of CSIP's alleged "control" over the Internet gatekeeper members at the PI hearing. *See* PI Tr. at 25:8-17 ("You have to be able to prove that CSIP controlled Bing, because presumably not all members have the same economic power or independence that Bing might have. So, I just – I don't understand how, if Bing decides to go along with this on its own, then - - [A:] As I said, your honor, ***we view this as a condition of Bing's participation in CSIP***, and I guess – The Court: So what? That assumes that they don't have some choice about whether or not they want to participate in CSIP. It just begs the question.") (emphasis added); *id.* at 26:16–27:23 ("Facebook – I read the stories. Facebook is so big, the government is trying to break it apart. This big, huge, giant behemoth is somehow on its knees begging for mercy from CSIP? Please don't kick us out of your association; we just don't want to blacklist this one website?... [A:] Nonetheless, *we believe these members are agents of CSIP* and would otherwise be bound" by CSIP's Principles of Participation.) (emphasis added).

do what CSIP tells it.") (emphasis added). More specifically, through these Principles of Participation, CSIP was purportedly able to force: (i) Google's and Microsoft's agreement to reduce Plaintiff's internet visibility; (ii) MasterCard's and PayPal's agreement to not process foreign drug purchases; and (iii) UPS's agreement not to ship drugs purchased from pharmacies outside the United States. Compl. ¶ 97 ("CSIP members . . . jointly agreed to only allow online pharmacies with a '.pharmacy' address to advertise, take payments, and ship products. In other words, the defendants now hold the keys to control online prescription drug markets.").[16] Aside from CSIP's *voluntary* Principles of Participation, Plaintiff alleges no *facts* supporting these alleged compulsory agreements. Moreover, there is simply no nexus alleged between the purported agreement(s) between certain CSIP members and any alleged agreement between the Defendants. The Court should reject as implausible under *Twombly* and its progeny Plaintiff's fanciful conspiracy theory—which requires the participation of all the Defendants and all or nearly all the so-called "gatekeepers," all of which, Plaintiff's allegations show, had independent motives to avoid the civil and criminal liability associated with facilitating the unlawful sale of foreign prescription drugs to individuals in the U.S. *See supra* notes 2, 6 and accompanying text.

Plaintiff's failure to allege facts establishing that Defendants collectively possessed a "conscious commitment to a common scheme designed to achieve an unlawful objective" further demonstrates the implausibility of its antitrust conspiracy claim. *Anderson News*, 680 F.3d at 184. Plaintiff's Complaint focuses chiefly on wholly *unilateral* action and conclusory allegations of certain Defendant's *attempts* to persuade others to agree to interfere with Plaintiff's contractual

[16] Plaintiff also complains that the .pharmacy domain serves a "gatekeeping function," letting companies like Google, Mastercard, and UPS to exclude even "the safest international pharmacy that sells into the United States." Compl. ¶¶ 96–97. It is not easy to see how this bears on the market for pharmacy verification services or "price comparison," or on PharmacyChecker's business if PharmacyChecker really is providing only "information" about these pharmacies. *See* Compl. at 1–2 (describing PharmacyChecker's provision of "information about lower-cost, safe prescription medicine"). If PharmacyChecker really were only providing information, not facilitating sales, it would be irrelevant that these international pharmacies cannot take payments from, or ship products to, U.S. consumers.

relationships with the so-called "gatekeepers." Unilateral acts cannot form the basis of a conspiracy as a matter of law. *Monsanto*, 465 U.S. at 761. Plaintiff asserts:

- NABP unilaterally approached "Google, Bing, and Yahoo!" *in 2008* "to persuade them to terminate their contracts with PharmacyChecker." Plaintiff fails to assert any facts establishing that any such agreement was ever reached, the terms of any purported agreement, or which gatekeeper purportedly reached agreement with NABP;
- NABP unilaterally added Plaintiff to the NRL in 2010, removed it in 2011 and unilaterally "blacklisted" Plaintiff by re-adding it to the NRL in 2018; and
- NABP unilaterally withheld VIPPS accreditation from one online U.S. pharmacy that worked with Plaintiff.

Compl. ¶ 78, 79, 82–83, 87. As decades of case law makes clear, Sherman Act Section 1 does not reach the conduct of a single firm: "[i]ndependent action is not proscribed." *Id.*

Plaintiff's allegations of bilateral meetings between some, but not all Defendants, and even business relationships between some individual Defendants and third parties, regarding broad, industry efforts to ensure patient safety, are also insufficient to establish conspiracy. Plaintiff lists two industry meetings occurring over eight years ago, one involving NABP and CSIP in early 2011 where the parties "discussed" curtailing unspecified websites "that promote online international pharmacy sales," i.e., illegal importation, and another between ASOP and NABP in 2012, where the parties "discussed numerous plans for actions they intended to undertake in conjunction with their co-conspirators to further limit competition from online pharmacies." Compl. ¶¶ 71–73. Plaintiff then alleges conduct by "some" CSIP *members* (but not CSIP itself) who were "persuaded" by NABP or who "reached private agreements" with NABP to "incorporate NABP's Not Recommended Sites list" on their own websites (e.g., Bing) and makes the wild inference that this was how Defendants "accomplished their plan." *Id.* ¶ 92. But bilateral meetings and "discussions," without more, hardly suffice to establish a meeting of the minds required under the Sherman Act. *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752, at *26 (S.D.N.Y. Sept. 22, 2015) (dismissing conspiracy allegations where plaintiffs' "overarching

conspiracy claim … lack[ed] sufficient factual support" because the complaint merely detailed bilateral agreements rather than coordinated action by all defendants, which was not "sufficient factual support" for coordinated action by all defendants), *aff'd in part, vacated in part, In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89 (2d Cir. 2017). It is implausible that Defendants hatched a scheme in 2012 but failed to implement it until NABP "blacklisted" Plaintiff in 2018 by placing it on the NRL with at least 11,000 other websites. *See* Compl. ¶ 87.

Plaintiff also includes irrelevant allegations of plainly lawful coordination, including allegations related to certain Defendants and others who worked with ICANN to create a ".pharmacy" domain extension. *See* Compl. ¶¶ 80–81. Courts are clear that industry efforts such as voluntary certifications by trade associations and standard setting organizations are not "walking conspiracies." *AD/SAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 234 (2d Cir. 1999) (upholding summary judgment for defendants; "we require a factual showing that each defendant conspired in violation of the antitrust laws, and have not adopted a 'walking conspiracy' theory in place of such a showing"); *Wilk v. Am. Med. Ass'n*, 895 F.2d 352, 374 (7th Cir. 1990) (affirming dismissal in favor of the defendants because the plaintiff failed to prove any antitrust injury: a trade association is not, just because it involves collective action by competitors, a 'walking conspiracy'"); *Consolidated Metal Products, Inc. v. American Petroleum Institute*, 846 F.2d 284, 292 (5th Cir. 1988) (holding that trade association's seal of approval for a particular product, without constraining others to follow the recommendation, does not violate antitrust laws). Again, Plaintiff is required to plead and ultimately prove a "meeting of minds." *Twombly*, 550 U.S. at 557. In the absence of such allegations, the Court should reject Plaintiff's argument.

Finally, Plaintiff asks the Court to infer a conspiracy from parallel behavior: in this case, Defendants and other advocacy organizations with similar interests and goals (promoting public

health and the safety of the drug supply) publishing purportedly similar language at different times flagging the very real risks that can arise from "internet drug outlets" or "online international pharmacy sales." Compl. ¶¶ 69–73, 85–86. But allegations of parallel conduct "must be placed in a context that raises a suggestion of a preceding agreement, not merely parallel conduct that could just as well be independent action." *Twombly*, 550 U.S. at 557; *Theatre Enters., Inc. v. Paramount Film Distrib. Corp.*, 346 U.S. 537, 541 (1954) ("[T]his Court has never held that proof of parallel business behavior conclusively establishes agreement, or … that such behavior itself constitutes a Sherman Act offense."). Plaintiff has not met this requirement. "A complaint alleging merely parallel conduct is not sustainable" and must be dismissed. *Anderson News*, 680 F.3d 184, *see also RxUSA Wholesale Inc. v. Alcon Labs*, 661 F. Supp. 2d 218, 231–32 (E.D.N.Y. 2009).

Thus, because Plaintiff's list of unilateral conduct, alleged attempts to "persuade" gatekeepers to reach certain agreements, and vague allegations of unremarkable trade group meetings years before any Defendant took any action cannot give rise to an inference of an unlawful "agreement," the Court should dismiss Plaintiff's claim. *See Twombly*, 550 U.S. at 557 (allegations must point toward meeting of minds), 566–67 (must plead facts that defendant did more than act consistently with its own, independent interest), 567 n.12 (trade group membership does not lead to inference of conspiracy).[17]

III. Plaintiff Fails to Plead Plausible Product and Geographic Markets.

Failure to sufficiently plead relevant markets in an antitrust case is grounds for dismissal. As the Court held in *Re-Alco Indus., Inc. v. Nat'l Ctr. for Health Educ., Inc.*, a "[p]laintiff must explain why the market it alleges is in fact the relevant, economically significant product market.

[17] As discussed in Defendants ASOP's and PSM's individual motions to dismiss, Plaintiff relies on alleged activity that is fully protected under the Noerr-Pennington doctrine. Defendants respectfully submit that, for the reasons stated in those briefs, the Court should disregard such allegations as facts supporting the existence of a conspiracy.

If a complaint fails to allege facts regarding substitute products, to distinguish among apparently comparable products, or to allege other pertinent facts relating to cross-elasticity of demand, as the complaint here fails to do, a court may grant a Rule 12(b)(6) motion." 812 F. Supp. 387, 391 (S.D.N.Y. 1993); *see also Apani Sw., Inc. v. Coca-Cola Enterprises, Inc.*, 300 F.3d 620, 628 (5th Cir. 2002) (affirming dismissal of the plaintiff's antitrust claims because "[w]here . . . the relevant market is legally insufficient . . . a motion to dismiss may be granted").

Market definition is essential to a plaintiff's antitrust claim because otherwise there is no context in which to determine whether the defendants' alleged conduct had anticompetitive effects. *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965). To define the market, Plaintiff must identify both: (1) the products at issue in the market (what consumers are buying); and (2) the market's geographic boundaries (where they are buying). *See Concord Assoc.'s LP v. Entm't Props. Trust*, 817 F.3d 46, 53 (2d Cir. 2015) (courts must "assess whether the plaintiffs' complaint asserts sufficient facts to allege plausibly the existence of both a product and geographic market."). Plaintiff fails to define either market.

A geographic market analysis "seeks to identify the precise geographic boundaries of effective competition." *Mathias v. Daily News, L.P.*, 152 F. Supp. 2d 465, 481 (S.D.N.Y. 2001). It "must be charted by careful selection of the market area in which the seller operates and to which the purchaser can practicably turn for supplies." *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961). Here, Plaintiff alleges a "worldwide" geographic market. Compl. ¶ 35. But mere assertions that modern markets are global or that "information services can be supplied from anywhere in the world" are insufficient. *Id.*; *In re Elevator Antitrust Litig.*, 502 F.3d 47, 52 (2d Cir. 2007) ("Plaintiffs provide an insufficient factual basis for their assertions of a worldwide conspiracy affecting a global market . . . plaintiffs offer nothing more than conclusory allegations:

for example, there are no allegations of global marketing or fungible products.").

Plaintiff's relevant geographic market allegations are conclusory; they contain none of the required facts relating to product interchangeability, demand cross-elasticity, or barriers to entry.[18] Any barriers to entry Plaintiff identifies in cursory fashion, were not "created" or "preserved" by Defendants. *See* Compl. ¶¶ 29, 50. They are a byproduct of the regulatory regime governing the manufacture and sale of prescription drugs. Consumers cannot *lawfully* turn to "Canadian or other non-U.S. pharmacies that sell medicine into the United States." *See Canadian Import*, 470 F.3d at 788–89. Thus, the relevant geographic market cannot be global as a matter of law.

Plaintiff likewise does not sufficiently plead relevant *product* markets. Product markets, like geographic markets, are defined with reference to interchangeability and cross-elasticity of demand. *Re-Alco*, 812 F. Supp. at 391. Plaintiff alleges two product markets: one for pharmacy price comparison services and one for online pharmacy accreditation services. *See* Compl. ¶ 30. Nowhere in the Complaint does Plaintiff attempt to define either product market through the lenses of interchangeability of products, cross-elasticity of demand, or any other accepted antitrust or economic rubric. The Court need not and should not credit Plaintiff's conclusory statements that assert, but fail to define, a relevant antitrust market. *See id*. ¶¶ 30-36. Indeed, to the extent Plaintiff has any *factual allegations* that could bear on market definition, it alleges that its verification services are "unique," i.e., not substitutable, when compared to companies like NABP, LegitScript, or the non-party Canadian International Pharmacy Association; they would therefore not be part of the same market. *See id*. ¶¶ 31, 33. And with respect to the alleged "market for comparative

[18] Plaintiff's reference in its geographic market allegations to the purported "substitutability" of "pharmaceutical *products*…from nation to nation" is irrelevant to the *geographic* market analysis. Compl. ¶¶ 36, 54–56 (emphasis added). First, if anything, while "pharmaceutical products" might constitute a relevant *product* market under circumstances not present here, Plaintiff does not assert pharmaceuticals as a relevant product market (and, in fact, explicitly disavows that it sells pharmaceuticals). *Id*. ¶¶ 30–34, 79. Second, the allegation is wrong as a matter of law because, as discussed, importation of pharmaceuticals into the United States is unlawful and therefore, at least for U.S. consumers, pharmaceutical products are not substitutable with those from other nations. *See supra* Background § 1.

prescription drug pricing information," Plaintiff does not allege that drug purchasers cannot easily turn to a host of alternative internet sources to find ubiquitous information about online pharmacies around the globe (i.e., the alleged geographic market). Nor does Plaintiff allege that any Defendant participates in the price comparison market. Compl. ¶¶ 30, 34 (listing one ASOP *member* as alleged competitor). Where no defendant participates in a market as a consumer or competitor, plaintiff must show that it was "manipulated or utilized by [defendants] as a fulcrum, conduit or market force to injure competitors or participants in the relevant product and geographic markets." *See In re Aluminum Warehousing Litig.*, 833 F.3d 151, 161 (2d Cir. 2016). Plaintiff alleges *no facts* to meet its burden.

IV. The Conduct Challenged by Plaintiff Does Not Warrant Departure from The Standard Rule-Of-Reason Analysis.

Plaintiff includes the legal conclusion that Defendants' efforts to bolster public health by promoting safe pharmacy practices in compliance with U.S. law are *per se* illegal. *See* Compl. ¶ 104. But *per se* illegality is reserved only for the most egregious of conduct—those rare "agreements whose nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality." *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 692 (1978) (noting that agreements that interfere with "the setting of prices by free market forces," such as price fixing or a code of ethics barring the discussion of prices before a professional can be hired meet the *per se* standard). Moreover, courts routinely decline to apply the *per se* rule, instead applying the rule of reason, where, as here, the alleged restraint relates to an ethical or industry standard reasonably designed to improve or protect public safety. *See, e.g., Wilk v. American Medical Ass'n*, 719 F.2d 207, 221 (7th Cir. 1983) (substantial evidence of a "patient care" motive rendered case inappropriate for *per se* rule); *Craftsmen Limousine, Inc. v. Ford Motor Co.*, 363 F.3d 761, 776 (8th Cir. 2004) (restraints based on safety concerns not

subject to *per se* treatment). Thus, the rule of reason applies to the conduct alleged by Plaintiff.

The rule of reason—a case-by-case, fact-based analysis—is the prevailing standard by which courts evaluate an alleged restraint of trade. *See, e.g.*, *Bogan v. Hodgkins*, 166 F.3d 509, 514 (2d Cir. 1999) (affirming summary judgment for defendants on alleged group boycott claim after applying rule of reason analysis, explaining that "[o]nly 'manifestly anticompetitive' conduct…is appropriately designated *per se* illegal. The majority of allegedly anticompetitive conduct continues to be examined under the rule of reason"); *see also Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49, 59 (1977); *Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006) ("[T]his Court presumptively applies rule of reason analysis…."); *Business Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 723 (1988) ("Ordinarily, whether particular concerted action violates § 1 of the Sherman Act is determined through case-by-case application of the so-called rule of reason."); *id.* at 726 ("[T]here is a presumption in favor of a rule-of-reason standard."). Plaintiff has not and cannot articulate a basis for departing from this rule.

V. Plaintiff's Antitrust Claims Is Barred by the Statute of Limitations.

A Sherman Act claim must be commenced "within four years after the cause of action accrued." 15 U.S.C. § 15b. At the very least, alleged conduct more than four years before the commencement of this action (August 13, 2015 and earlier) should not be considered here. This is because plaintiffs may only recover damages based on acts falling within the statutory period, and not based on previous acts. *See Hinds Cty., Miss. v. Wachovia Bank N.A.*, 620 F. Supp. 2d 499, 519 (S.D.N.Y.2009) (dismissing the plaintiffs' claims against a number of defendants because the claims were based on events outside the statute of limitations and the plaintiffs failed to adequately plead fraudulent concealment, explaining that the plaintiffs could proceed on a claim against the defendants "if it is based on an overt act that occurred within the statute of limitations, but they can only recover damages based on those acts, and not based on previous acts").

Here, the vast majority of Plaintiff's allegations fall well outside the four-year period prior to filing commencement of this action on August 13, 2019. Plaintiff bases its claims on conduct dating back to 2008. *See* Compl. ¶ 78 (2008); *see also id*. at ¶¶ 69 (2010), 70 (2010), 71 (2011), 72 (2012), 73 (2012). But it inexplicably waited ***over eleven years*** to file its Complaint. At the latest, Plaintiff knew or should have known about the purported conduct that gave rise to its claims ***over nine years ago***, as Plaintiff challenges NABP's placing it on the NRL in 2010. *Id*. ¶ 79. This is plainly untimely and Plaintiff points to no facts justifying its delay in bringing this action.[19]

VI. Plaintiff Has Not and Cannot Plead Facts Sufficient to State a Lanham Act Claim.

Plaintiff fails to plead facts establishing essential elements of a Lanham Act claim: "(1) that the [challenged] statements were false; (2) that they were used in commercial advertising or promotion; and (3) that this advertising or promotion misrepresents the nature, characteristics, qualities, or geographic origin of an inherent quality or characteristic of Plaintiff or Defendant's products." *See Chamilia, LLC v. Pandora Jewelry, LLC*, Case No. 04-CV-6017 (KMK), 2007 WL 2781246, at *6 (Sept. 24, 2007) (citing 15 U.S.C. § 1125(a)(1)(B)); *see also Gmurzynska v. Hutton*, 355 F.3d 206, 210 (2d Cir. 2004); *Lokai Holdings LLC v. Twin Tiger USA LLC*, 306 F. Supp. 3d 629, 638 (S.D.N.Y. 2018). NABP's statements are not false, they do not constitute "commercial advertising," and they do not misrepresent the nature of Plaintiff's product.[20]

[19] The law is clear that "[i]f the allegations…show that relief is barred by the applicable statute of limitations, the complaint is subject to dismissal for failure to state a claim." *Jones v. Bock*, 549 U.S. 199, 215 (2007); *see also generally Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 76 (2d Cir. 1998). As courts have long held, "[s]tatutes of limitations are not simply technicalities. On the contrary, they have long been respected as fundamental to a well-ordered judicial system." *Bd. of Regents of Univ. of State of N. Y. v. Tomanio*, 446 U.S. 478, 487 (1980); *see also Carey v. Int'l Bhd. of Elec. Workers Local 363 Pension Plan*, 201 F.3d 44, 47 (2d Cir. 1999) ("[S]trict adherence to limitation periods is the best guarantee of evenhanded administration of the law.")

[20] Plaintiff has not alleged any facts to satisfy the prong that the challenged NABP statements "misrepresent the nature, characteristics, qualities, or geographic origin of an inherent quality or characteristic of [its] products." *See generally*, Compl. To the extent Plaintiff alleges that NABP's NRL statements regarding the illegality of importation misrepresents Plaintiff's products, this claim necessarily fails because, as discussed, importation is illegal and unsafe and Plaintiff concededly facilitates illegal purchases. *See, e.g., Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51,

A. Plaintiff Has Not Pled Facts Sufficient to Show Falsity.

Plaintiff must show Defendant's statements are either literally or impliedly false. *See Lokai*, 306 F. Supp. 3d at 638–39 (dismissing Lanham Act claim because statement that product "carries water", in the court's "own common sense and logic in interpreting the message of the advertisement," was neither literally nor impliedly false). "For a statement to be 'literally false' or false on its face, it must conflict with reality." *Id.* "Under the literally false theory, the message must be unambiguous; if the representation is susceptible to more than one reasonable interpretation, [it] cannot be literally false…." *Id*. (internal quotation omitted).

Alternatively, to be impliedly false, Plaintiff must establish that the statement is "likely to mislead or confuse consumers" and that "the challenged advertising…, whatever its literal truth, has left an impression on the listener that conflicts with reality." *Id*. "At the pleading stage, the plaintiff must allege that consumers or retailers were misled or confused by the challenged advertisement and '*offer facts* to support that claim.'" *Id.* (emphasis in original).

A summary of each of NABP's challenged statements and the reasons Plaintiff has not and cannot plead facts establishing literal or implied falsity follows in Table I.

1. NABP Statements Are Not Literally False

None of NABP's statements are false on their face or "conflict with reality." *See Lokai*, 306 F. Supp. 3d at 638. As personal importation is virtually always illegal, *see supra* Background § 1, NABP's statements that NRL sites "may [r]efer/link patients to sites that facilitate the dispensing of prescription medications in violation of law" or "appear[] to be out of compliance with state and federal laws" cannot be literally (or impliedly) false. Compl. ¶ 119.

63 (2d Cir. 2016) (Plaintiff "must also demonstrate that the false or misleading representation involved an inherent or material quality of the product," defined as "likely to influence purchasing decisions."); *Lokai*, 306 F. Supp. 3d at 639 Fn.3 (noting that there is a materiality requirement under both literal and implied falsity theories).

It is also hardly false for *NABP* to represent its opinion that NRL sites "appear to be out of compliance *with NABP['s own]* patient safety and pharmacy practice standards" or "refer patients to websites that operate in violation of *NABP['s own]* patient safety and pharmacy practice standards." Compl. ¶ 119 (emphasis added). *See Davis v. Avvo, Inc.*, 345 F. Supp. 3d 534, 541 (S.D.N.Y. 2018) (defendant's "inherently subjective" attorney rating system not actionable: "A reasonable consumer would view an Avvo rating as just that – the defendant's evaluation. What factors the defendant believes to be important . . . , and the result of the defendant's weighing of those factors, cannot be proven false.").[21] Reasonable consumers would view NABP's NRL and "safety-related" statements as NABP's own subjective assessment.

NABP's statements about relative "risk," "safety," and "best practices" are also subjective opinion statements that cannot, by definition, qualify as false representations. Plaintiff's own allegations prove the point that terms like "safe," "safer," "safety, "and "at risk" are matters of subjective opinion; they are not unambiguous, are susceptible to numerous interpretations, and are thus incapable of being proven false as a matter of law.[22] *See Fischer v. Forrest*, 286 F. Supp. 3d 590, 618 (S.D.N.Y. 2018) (no literal falsity where "[Plaintiff]'s allegations in his complaint, which assign alternative interpretations to [statement at issue], underscore its uncertain meaning."); *see*

[21] *See also Groden v. Random House, Inc.*, No. 94-cv-1074, 1994 WL 455555, at *5 (S.D.N.Y. Aug. 23, 1994) (Defendant's advertising labeling plaintiff's book on the Kennedy assassination as "GUILTY OF MISLEADING THE AMERICAN PUBLIC" was opinion and such "[s]ubjective claims about products, which cannot be proven either true or false, are not actionable under the Lanham Act."), *aff'd*, 61 F.3d 1045 (2d Cir. 1995). *See generally Center for Immigration Studies v. Cohen*, 410 F. Supp. 3d 183, 190 (D.D.C. 2019) (Plaintiff had no actionable claim against defendant SPLC for designating plaintiff's organization as a hate group on SPLC's "Hatewatch" blog because "whether or not SPLC adhered to its [own] definition to designate CIS to be a hate group is an entirely subjective inquiry.").

[22] *See, e.g.*, Compl. ¶ 5 (Plaintiff "inform[s] consumers of legitimate pharmacies that observe safe pharmacy practices…"); ¶ 127 ("PharmacyChecker.com ***improves*** consumer safety;" "when consumers purchase medicine through PharmacyChecker.com-accredited pharmacy websites, they are safer") (emphasis in original); ¶ 132 ("nothing inherently unsafe about personal importation"). In Plaintiff's view, personal importation is "safe" because, for example, it is "belied by…programs run by self-insured entities in the United States…[which] have had no safety complaints and have saved money" and "[t]he FDA has never reported even a single instance of death" from drugs obtained by personal importation. *Id.* ¶ 132a–d.

also Lokai, 306 F. Supp. 3d at 638 (dismissing literal falsity claim because phrase "carries water" is susceptible to more than one reasonable interpretation); *Classic Liquor Importers, Ltd. v. Spirits Int'l B.V.*, 201 F. Supp. 3d 428, 453 (S.D.N.Y. 2016) (literal falsity counterclaim failed due to qualifying language showing multiple reasonable interpretations of phrase "Since 1867."); *W.L. Gore & Associates, Inc. v. Totes, Inc.*, 788 F. Supp. 800, 808 (D. Del. 1992) ("breathable" product claim was a subjective, non-factual statement meaning different things to different people.).

Even if the Court construes NABP's safety-related representations as statements of fact, the law establishes that personal importation is "unsafe" and "risky." *Canadian Import*, 470 F.3d at 789 ("[t]he FDA's Office of Compliance has cautioned that 'drugs from foreign countries do not have the same assurances of safety as drugs actually regulated by the FDA due to the risk that counterfeit or unapproved drugs will be sent to consumers…."); *see also id.* (FDCA is "designed to guarantee safe…drugs for consumers in the United States."); *id.* at 790 ("The [FDCA's] approval process addresses…the drug's safety…."). The FDA reiterated as recently as December 2019 that "[m]edications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges to the FDA and its ability adequately safeguard the quality and safety of drugs taken by U.S. consumers." HHS Proposed Drug Importation Rule, 84 Fed. Reg. at 70800. Thus, when consumers purchase foreign pharmaceuticals, it is true that they will by definition lack the "assurances of safety" guaranteed by the FDA's "closed system." *Canadian Import*, 470 F.3d at 790.

Finally, most of NABP's statements at issue are disjunctive and qualified and cannot be false as a matter of law. Disjunctive statements cannot be literally false where at least one clause is plainly true. *See Border Collie Rescue, Inc. v. Ryan*, 418 F. Supp. 2d 1330, 1347 (M.D. Fla. 2006) (statement that defendant "trained or worked with" dogs not literally false; defendant

worked with dogs and "use of the disjunctive [with one true clause] removes the representation from the purview of a literal falsity…."). Given this, representations including that NRL sites "**appear** to be out of compliance with state and federal laws, **or** NABP patient safety and pharmacy practice standards," or "Using websites on the NRL to purchase drugs **may** put you or your loved ones at risk" cannot be false as matter of law. Compl. ¶¶ 119–123; (Table I # 2, 3, 8).

2. NABP Statements Are Not Impliedly False.

In the absence of literal falsity, a plaintiff must put forth *facts* establishing that statements are impliedly false. *Lokai*, 306 F. Supp. 3d at 638. For a statement to be impliedly false, a plaintiff must show that "the challenged advertising…has left an impression on the listener" that would be "likely to mislead or confuse consumers." *Id.* Given the accuracy of each of the NABP's alleged factual representations, as discussed immediately above, *supra* Section VI.A.1, NABP's statements could not cause consumer confusion.

Plaintiff claims that NABP deceives consumers and internet "gatekeepers" by: (i) stating or implying that personal importation is illegal and/or unsafe; and (ii) "conflating" Plaintiff's site, which does not directly sell foreign drugs, with NRL sites that directly import into the U.S. *See* Compl. ¶¶ 126, 128, 130–132. There can be nothing impliedly false about such representations. As discussed, personal importation of foreign pharmaceuticals is virtually always illegal. *See supra* Background § 1. And while Plaintiff does not directly sell foreign drugs to U.S. consumers, it represented to the Court, as it must, that the "primary" purpose it provides information (and links to foreign internet pharmacies) to consumers is to "facilitate" unlawful drug importation. *See supra* Section II.A. Given this, NABP's NRL statements cannot "conflict with reality" or mislead consumers or sophisticated internet gatekeepers like Google or Bing/Microsoft.

Moreover, the Court should disregard Plaintiff's allegations of consumer deception as factually unsupported. *Lokai*, 306 F. Supp. 3d at 639 (dismissing Lanham Act claim where

plaintiff "offer[ed] no facts that show[ed] that consumers or retailers believed [statement]… or that this belief likely influenced their purchasing decisions").[23] Plaintiff offers only naked assertions that various audience groups are likely to have been misled by NABP statements. *See, e.g.*, Compl. ¶136 (Consumers and internet service providers "are likely to be, and actually have been, deceived by the statements made by NABP"); ¶ 124 (NABP pages "frighten consumers away from a listed site while directing them to NABP affiliates"); ¶ 134 (NABP "has caused PharmacyChecker.com competitive harm by deceiving consumers"). But unsupported assertions that consumers and retailers purchased products or used a service based on a false belief, without facts showing that consumers or retailers actually held the allegedly false belief, are not enough at the pleading stage. *See Liberty Counsel, Inc. v. GuideStar USA, Inc.*, 737 F. App'x 171, 172 (4th Cir. 2018) (dismissing complaint as "insufficient to state a violation of the Lanham Act" because "other than identifying a broad swath of people whom the banner allegedly deceived, plaintiff baldly alleged customer confusion without providing 'further factual enhancement,'" explaining "a complaint must state facts demonstrating that the defendant's liability is plausible, not merely possible.") (citing *Iqbal*, 556 U.S. at 662).

Moreover, alleged lost web traffic alone is not generally sufficient to show harm. *See Davis*, 345 F. Supp. 3d at 544 (plaintiff failed to sufficiently allege injury when plaintiff merely pointed to defendant's prominent presence in internet search results, rather than asserting facts showing that potential clients were dissuaded from hiring plaintiff because of anything that has appeared on defendant's website). "Alleging that the defendant's website has high visibility on the internet does not change the plaintiff's mere subjective belief of harm into something more." *Id.*

[23] For example, consumer surveys have commonly been used as factual support for actual consumer confusion. *See Clorox Co. Puerto Rico v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 36 (1st Cir. 2000) ("[P]ropensity to deceive the viewing public is most often proven by consumer survey data.").

Plaintiff thus pleads no facts supporting its claim that consumers were deceived. Such bare allegations are insufficient to proceed under an implied falsity theory.

B. Plaintiff Has Not Pled Facts Sufficient to Show that NABP's Statements Were Made in "Commercial" Advertising or Promotion.

The Lanham Act covers only statements made "in commercial advertising or promotion." *Gmurzynska*, 355 F.3d at 210. The statement must be: (1) "commercial speech," (2) made "for the purpose of influencing consumers to buy defendant's goods or services," and (3) "disseminated sufficiently to the relevant purchasing public." *Id.* Commercial advertising or promotion is "speech which does no more than propose a commercial transaction." *Id.* at 210; *Navarra v. Marlborough Gallery, Inc.*, 820 F. Supp. 2d 477, 488 (S.D.N.Y. 2011).

NABP's statements are not commercial speech as a matter of law. "[T]he Supreme Court's *broadest* definition for commercial speech is an expression related *solely* to the economic interests of the speaker and its audience." *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 455, 457 (D.N.J. 2009) (emphasis added) (citing *City of Cincinnati v. Discovery Network, Inc*., 507 U.S. 410, 422 (1993)). Where, as here, there is a public purpose beyond the "solely commercial," the speech is fully protected by the First Amendment and not within reach of the Lanham Act. *See id.* (statements had "educational purpose [] which fall[] far short of the "solely commercial" requirement); *Gordon & Breach Sci. Publishers S.A. v. Am. Inst. Of Physics*, 859 F. Supp. 1521, 1539-41 (S.D.N.Y. 1994) ("*G&B*") (Lanham Act does not cover statements that "raise free speech concerns, such as a Consumer Report which reviews and may disparage the quality… of products, [and] misrepresentations made by interested groups which may arguably disparage a company and its products.") (citing S. 1883, 101st Cong., 1st Sess., 135 Cong. Rec. 1207, 1217 (April 13, 1989); *Boule v. Hutton*, 328 F.3d 84, 91–92 (2d Cir. 2003) ("[W]e have been careful not to permit overextension of the Lanham Act to intrude on First Amendment values."); *Wojnarowicz*

v. Am. Family Ass'n, 745 F. Supp. 130, 141 (S.D.N.Y. 1990) (The Act "has never been applied to stifle criticism of the goods or services of another by one[] such as a consumer advocate.").

For example, in *G&B*, this court addressed "speech which, from one perspective, presents the aspect of protected, noncommercial speech addressing a significant public issue, but which, from another perspective, appears primarily to be speech 'proposing a commercial transaction.'" 859 F. Supp. at 1539. The court held that the challenged statements, a survey of academic articles' cost and comparative quality that ranked defendants' own journals higher than plaintiff's, in fact "fall decidedly on the noncommercial, fully protected side of the line." *Id*. at 1540. No one factor was dispositive, but the court held that defendants were, like NABP, non-profit entities that have purposes beyond the solely commercial the "implicate significant First Amendment concerns." *Id*. "Such noncommercial purposes are constitutionally significant even when they are intertwined with commercial aspects." *Id*. Thus, "[t]he fact that [defendants] stood to benefit from publishing [the challenged article rating] results—even that they intended to benefit—is insufficient by itself to turn the articles into commercial speech." *Id*.

Similarly, in *Davis v. Avvo, Inc.*, the court considered a website that maintained profiles of attorneys and rated their quality to allow consumers "to access information about, find, and vet attorneys." 345 F. Supp. 3d 534, 539 (S.D.N.Y. 2018). The court dismissed plaintiff's Lanham Act claim against the website because the challenged features "do not constitute commercial speech;" rather, "[t]he ratings…are statements of opinion protected by the First Amendment." 345 F. Supp. 3d at 540. Specifically, the "complained-of website features simply provide information; they might be considered [by consumers] in making, but do not themselves propose, a commercial transaction. Moreover, that sponsored advertisements appear on the defendant's website does not morph the website's noncommercial features into commercial speech." *Id*.

Here, Plaintiff's conclusory allegations that the NRL was "designed to promote the goods and services of NABP and its affiliates" are insufficient as a matter of law to convert NABP's statements into commercial speech. Compl. ¶135; *see Davis*, 345 F. Supp. 3d at 539–40 (dismissing Lanham Act claim even when plaintiffs alleged that defendant was paid to give certain attorneys higher ratings, because the ratings were still not commercial speech and do not propose a commercial transaction). The closest Plaintiff comes to a factual allegation is that the NABP statements "propose commercial transactions" because they tell consumers to "'Buy safely' with a link to a list of NABP *affiliates*" and "dissuade consumers from making other commercial transactions" such as ordering drugs from websites on the NRL. Compl. ¶ 134 (emphasis added). This cannot be sufficient to move a statement from advocacy to "commercial speech," as virtually all consumer advocacy recommends that consumers use certain products or dissuade them from using others for reasons of quality, safety, legality, or simply idiosyncratic preference. For this reason and those considered in *G&B* and *Davis*, courts routinely dismiss Lanham Act claims against consumer advocacy groups like NABP engaged in public policy advocacy speech. *G&B*, 859 F. Supp. at 1541 ("Non-profit organizations must be free to participate fully in the marketplace of ideas without fear of sanctions, even if such participation redounds to their financial benefit.").

CONCLUSION

For all the foregoing reasons, Defendants respectfully request that the Court dismiss Plaintiff's Sherman Act § 1 claim and Defendant NABP respectfully requests that the Court dismiss Plaintiff's Lanham Act claim.

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Table I (Compl. ¶¶ 119-125; Exhs E–H.) (emphases added)[24]

#	Statement	Not False
1	"Avoid These Websites"	A, B
2	"Not Recommended Sites are those internet drug outlets that **appear** to be out of compliance with state and federal laws **or** NABP patient safety and pharmacy practice standards. Such sites **may**: • Dispense prescription medicine without a prescription • Dispense foreign or unapproved medicine [**or**] (Compl. ¶ 119) • Refer/link patients to sites that facilitate the dispensing of prescription medications in violation of state or federal law **or** NABP standards. Ordering from these websites puts you and your family at **risk**."	B; C (facilitate); D; E; F
3	"NABP's Not Recommended List (NRL) includes those websites that **appear** to be out of compliance with NABP patient safety and pharmacy practice standards, **or** applicable law. Websites on NABP's NRL commonly **facilitate**: • the sale of prescription-only medicine without requiring a valid prescription; • the sale of medicine that has not been approved **or** authorized for sale in the patient's jurisdiction; • the practice of pharmacy without required licensure in all relevant jurisdictions. Some websites on the NRL do not sell drugs directly. Instead, they refer patients to websites that operate in violation of NABP patient **safety** and pharmacy practice standards, **or** applicable law."	B, C (facilitate); D; E; F
4	NRL sites are "acting illegally **or** do not follow best practices."[25]	B; D; E; F
5	"Search the **unsafe** sites list"	B; E; F
6	"The following sites are on NABP's Not Recommended List"[26]	C
7	"The following sites are all known to be **unsafe**"	B; E; F
8	"Using websites on the NRL to purchase drugs may put you or your loved ones at **risk**"	D; E; F
9	"Buy **safely**"	A; B; E; F
10	"Purchase medication from **legitimate** websites online"	A; B; E

[24] Legend:
A: Not a factual assertion
B: Opinion
C: Plaintiff concedes truth
D: Qualified/disjunctive
E: Susceptible to more than one reasonable interpretation
F: Consistent with U.S. law re relative safety of foreign pharmacies

[25] This statement is referenced in Compl. ¶ 120 but does not appear in Plaintiff's videos shown in Exhs. E–H.

[26] This statement is referenced in Compl. ¶ 120 but does not appear in Plaintiff's videos shown in Exhs. E–H.